



CANDELA

JUL 13 2005

510(k) Summary

General Information:

This 510(k) is to provide notification of substantial equivalence for the Candela Family of Pulsed Dye Lasers Pigmented Lesion Handpiece Accessory is indicated for use with the Candela Family of Pulse Dye Lasers for the Treatment of Benign Epidermal Pigmented Lesions.

Submitted by: Candela Corporation
530 Boston Post Road
Wayland, MA 01778-1886

Contact Person: Lorraine Calzetta

Date prepared: May 13, 2005

Classification: Class II (21 CFR § 878.4810 Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology)

Common Name: Dermatology Laser, Candela Family of Pulse Dye Laser Systems

Predicate Devices:

Candela Family of Pulsed Dye Lasers - K043251
MSQ Family of Laser/Light System Handpieces - K040200
Lumenis Light Sheer – K001746

Description:

The Candela Family of Pulsed Dye Laser Systems are 585, 595nm flash-lamp excited pulse dye medical lasers, indicated for the following uses:

The laser output energy is delivered via an optical fiber to a handpiece, which produces circular beams or elliptical beams on the skin.. The Pigmented Lesion Handpiece Accessory attaches to the standard handpiece and replaces the standard distance gauge for the treatment of benign epidermal pigmented lesions

The Candela Family of Pulsed Dye Laser Systems is equipped with safety interlock systems to protect patients and operators. Users of the device make selections from an onboard control panel to regulate operation during treatment.

The pigmented lesion handpiece accessory is designed for use with the Candela Pulsed Dye Laser handpiece, for the treatment of Benign Epidermal pigmented Lesions

Testing:

As a laser product, the Candela Family of Pulsed Dye Laser Systems conforms to the CDRH Laser Performance Standard (21 CFR 1040). And IEC 60601-1.Electrical Safety Standard.

All materials contacting the patient conform to the requirements Of the FDA recognized consensus standard ISO 10993-1.

Summary of Substantial Equivalence:

On the basis of similarities in key design aspects, intended uses and materials, Candela Corporation believes that its Candela Family of Pulsed Dye Laser Systems Pigmented Lesion Handpiece Accessory is substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2005

Ms. Lorraine Calzetta Patrovic
Manager, Regulatory Affairs
Candela Corporation
530 Boston Post Road
Wayland, Massachusetts 01778

Re: K051359

Trade/Device Name: Candela Family of Pulsed Dye Laser Systems: Pigmented Lesion
Handpiece Accessory

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and
plastic surgery and in dermatology

Regulatory Class: II

Product Code: GEX

Dated: May 20, 2005

Received: May 24, 2005

Dear Ms. Patrovic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Ms. Lorraine Calzetta Patrovic

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Miriam C. Provost, Ph.D.

Acting Director

Division of General, Restorative

and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051359

Device Name:

Candela Family of Pulsed Dye Laser Systems : Pigmented Lesion Handpiece
Accessory

Indications For Use:

- The Candela Family of Pulse Dye Laser Systems Pigmented Lesion Handpiece Accessory is indicated for the ***Treatment of Benign Epidermal Pigmented Lesions***

Prescription Use X
(Part 21 CFR 801 Subpart D)


AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1


(Division Sign-Off)
Division of General, Restorative
and Neurological Devices
510(k) Number K051359